

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

BAUSCH HEALTH IRELAND
LIMITED, *et al.*,

Plaintiffs,

v.

PADAGIS ISRAEL PHARMACEUTICALS
LIMITED, *et al.*,

Defendants.

Civil Action No. 20-5426 (SRC) (CLW)
(CONSOLIDATED)

Document Electronically Filed

**STIPULATION AND ORDER
REGARDING INFRINGEMENT**

WHEREAS, in light of the Court's Claim Construction Opinion and Order (ECF No. 83), the Stipulation and Order on Supplemental Claim Constructions (ECF No. 105), and the Court's Opinion & Order dated September 21, 2022 (ECF No. 196), Plaintiffs Bausch Health Ireland Limited, Bausch Health Americas, Inc., and Bausch Health US, LLC (collectively, "Bausch" or "Plaintiffs"), and Defendants Padagis Israel Pharmaceuticals Limited and Padagis US LLC (collectively, "Padagis" or "Defendants") agree to enter into this stipulation regarding the Asserted Claims of U.S. Patent Nos. 10,251,895 and 10,426,787 to further narrow the disputed issues in the case;

WHEREAS the Court's Opinion and Order (ECF No. 196) granting Plaintiffs' motion *in limine* Nos. 1 and 3 and granting in part Plaintiffs' motion *in limine* No. 4 has the effect of precluding Padagis's infringement defense related to statistical significance;

WHEREAS, in view of the rulings specified above, Padagis agrees to enter into stipulations that both Padagis's Halobetasol and Tazarotene ANDA Product and Bausch's Duobrii® Product are covered by the asserted claims of two patents Bausch has asserted in this Action, U.S. Patent Nos. 10,251,895 and 10,426,787, subject to Padagis's right of appeal,

including appeal of infringement of the Asserted Claims of U.S. Patent Nos. 10,251,895 and 10,426,787;

NOW THEREFORE, Plaintiffs and Defendants further stipulate and agree as follows:

1. Padagis Israel Pharmaceuticals Limited has submitted Abbreviated New Drug Application No. 214626 (“Padagis’s Halobetasol and Tazarotene ANDA”) seeking approval to market a generic halobetasol and tazarotene topical lotion, 0.01%/0.045% (“Padagis’s Halobetasol and Tazarotene ANDA Product”).

2. Bausch asserts in this Action (*inter alia*) that Padagis infringed claims 3 and 6 of U.S. Patent No. 10,251,895, and claims 4, 5, and 7 of U.S. Pat. No. 10,426,787 (collectively, the “Asserted Claims of U.S. Patent Nos. 10,251,895 and 10,426,787”) under 35 U.S.C. § 271(e)(2) by the submission of Padagis’s Halobetasol and Tazarotene ANDA, and would also infringe the same claims (directly or indirectly) under 35 U.S.C. § 271(a)-(c) by making, using, offering to sell, or selling Padagis’s Halobetasol and Tazarotene ANDA Product.

3. Padagis stipulates, in light of the rulings above, that the submission of Padagis’s Halobetasol and Tazarotene ANDA to the FDA infringed each of the Asserted Claims of U.S. Patent Nos. 10,251,895 and 10,426,787.

4. Padagis stipulates that, in light of the rulings above, the manufacture, use, offer to sell, sale, and/or importation of Padagis’s Halobetasol and Tazarotene ANDA Product would infringe each of the Asserted Claims of U.S. Patent Nos. 10,251,895 and 10,426,787.

5. Padagis and Bausch stipulate that, in light of the rulings above, Bausch’s Duobrii® Product (also identified as IDP-118) embodies each of the Asserted Claims of U.S. Patent Nos. 10,251,895 and 10,426,787. For the avoidance of doubt, Bausch maintains its position that Bausch’s Duobrii® Product (also identified as IDP-118) embodies each of the Asserted Claims of U.S. Patent Nos. 10,251,895 and 10,426,787 irrespective of the rulings above.

6. The Parties stipulate that, in light of this stipulation and the Court's rulings above, neither Plaintiffs nor Defendants will call Dr. Philip Lavin or Dr. Rebecca Betensky at trial, or any other witness on the issue of infringement.

7. The parties agree that the foregoing stipulation and agreement is made without prejudice to Padagis's positions regarding the invalidity of the Asserted Claims and without prejudice of any right to appeal, including appeal of infringement of the Asserted Claims of U.S. Patent Nos. 10,251,895 and 10,426,787.

SO STIPULATED:

Dated: September 23, 2022

s/ William P. Deni, Jr.

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Dated: September 23, 2022

s/ Karen A. Confoy

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SO ORDERED this 26th day of September, 2022:

s/ Stanley R. Chesler

Hon. Stanley R. Chesler, U.S.D.J.